



Drug Information

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Paragraph IV Patent Certifications As of July 1, 2002

The Agency is making available, on a trial basis, a list of drug products for which an Abbreviated New Drug Application (ANDA) has been received by the Office of Generic Drugs (OGD) containing a "Paragraph IV" patent certification. This list includes the name of the drug product, dosage form, strength (subject of Paragraph IV certification), and reference listed drug (RLD). The Agency will not disclose when the ANDA was received by the Office of Generic Drugs or the identity of the applicant. This information will be updated on a monthly basis and will be as current as the last update. This information should be used for reference only. The Agency will make every effort to ensure the accuracy of the information disclosed in this list. However, any discrepancies or disparities should be discussed with the Regulatory Support Branch at 301-827-5862, before making any decisions based on this information. **Additions to this month's list are in red.**

| DRUG NAME | DOSAGE FORM | STRENGTH | RLD |
|----------------------------------|--------------------------|--------------------------------------|---------------------|
| Acetaminophen | Extended-release Tablet | 650 mg | Tylenol |
| Acetaminophen/ Aspirin/ Caffeine | Tablet | 250 mg/ 250 mg/ 65 mg | Excedrin (migraine) |
| Acyclovir Sodium | Injection | 50 mg/mL, 10 mL and 20 mL vials | Zovirax |
| Albuterol Sulfate | Oral Syrup | 2 mg(base)/ 5 mL | Ventolin |
| Albuterol Sulfate | Tablets | 4 mg and 8 mg | Volmax |
| Alendronate Sodium | Tablets | 5 mg, 10 mg, 35 mg, 40 mg and 70 mg | Fosamax |
| Alprazolam | Tablets | 0.25 mg, 0.5 mg, 1 mg and 2 mg | Xanax |
| Atenolol | Tablets | 25 mg, 50 mg and 100 mg | Tenormin |
| Atenolol/ Chlorthalidone | Tablets | 50 mg/ 25 mg and 100 mg/ 25 mg | Tenoretic |
| Betaxolol | Ophthalmic Solution | 0.5%(base) | Betoptic |
| Brimonidine Tartrate | Ophthalmic Solution | 0.2% | Alphagan |
| Bupropion Hydrochloride | Extended-release Tablet | 150 mg | Zyban |
| Bupropion Hydrochloride | Extended-release Tablets | 100 mg and 150 mg | Wellbutrin SR |
| Bupropion Hydrochloride | Tablets | 75 mg and 100 mg | Wellbutrin |
| Buspiron Hydrochloride | Tablets | 5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg | Buspar |
| Butorphanol Tartrate | Nasal Spray | 10 mg/mL | Stadol NS |
| Calcitriol | Injection | 1 mcg/mL and 2 mcg/mL, 1 mL vials | Calcijex |
| Captopril | Tablets | 12.5 mg, 25 mg, 50 mg, and 100 mg | Capoten |

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| Carbamazepine | Extended-release Tablet | 200 mg and 400 mg | Tegretol XR |
| Carbidopa/ Levodopa | Extended-release Tablets | 25 mg/ 100 mg and 50 mg/ 200 mg | Sinemet CR |
| Carboplatin | For Injection | 50 mg/vial, 150 mg/vial and 450 mg/vial | Paraplatin |
| Carboplatin | Injection | 50 mg/vial, 150 mg/vial and 450 mg/vial | Paraplatin |
| Carisoprodol/ Aspirin | Tablet | 200 mg/ 325 mg | Soma Compound |
| Carisoprodol/ Aspirin/Codeine | Tablet | 200 mg/ 325 mg/ 16 mg | Soma Compound with Codeine |
| Carvedilol | Tablets | 3.125 mg, 6.25 mg, 12.5 mg and 25 mg | Coreg |
| Chlorhexidine Gluconate | Scrub brush/sponge | 4% | Hibiclens |
| Ciprofloxacin Hydrochloride | Tablets | 100 mg, 250 mg, 500 mg and 750 mg | Cipro |
| Cisplatin | Injection | 1 mg/mL, 10 mL, 50 mL, 100 mL and 200 mL vials | Platinol-AQ |
| Cisplatin | For Injection | 10 mg/vial and 50 mg/vial | Platinol |
| Clonidine Hydrochloride | Transdermal System | 0.1 mg/day, 0.2 mg/day, and 0.3 mg/day | Catapres-TTS |
| Clopidogrel Bisulfate | Tablet | 75 mg | Plavix |
| Cyclobenzaprine Hydrochloride | Tablet | 10 mg | Flexeril |
| Cyclophosphamide | For Injection | 100 mg/vial, 200 mg/vial, 500 mg/vial, 1 g/vial and 2 g/vial | Cytosan |
| Desmopressin Acetate | Injection | 4 mcg/mL, 1 mL and 10 mL vials | DDAVP |
| Desmopressin Acetate | Nasal Solution (nasal spray) | 0.01% | DDAVP |
| Dexrazoxane | For Injection | 250 mg/vial | Zinecard |
| Diazepam | Tablets | 2 mg, 5 mg and 10 mg | Valium |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg and 240 mg | Dilacor XR |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg, 240 mg, 300 mg and 360 mg | Tiazac |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg, 240 mg and 300 mg | Cardizem CD |
| Diltiazem Hydrochloride | Extended-release Capsules | 60 mg, 90 mg and 120 mg | Cardizem SR |
| Divalproex Sodium | Delayed-release Tablets | 125 mg, 250 mg and 500 mg | Depakote |
| Doxazosin Mesylate | Tablets | 1 mg, 2 mg, 4 mg and 8 mg | Cardura |
| Enalapril Maleate | Tablets | 2.5 mg, 5 mg, 10 mg and 20 mg | Vasotec |

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| Esmolol Hydrochloride | Injection | 10 mg/mL, 10 mL vial | Brevibloc |
| Estradiol | Transdermal System | 0.05 mg/day and 0.1 mg/day | Climara |
| Etodolac | Extended-release Tablets | 400 mg, 500 mg and 600 mg | Lodine XL |
| Famotidine | Tablet | 10 mg (OTC) | Pepcid AC |
| Famotidine | Tablets | 20 mg and 40 mg | Pepcid |
| Famotidine | Injection | 10 mg/mL, 4 mL and 20 mL vials; preserved | Pepcid |
| Famotidine | Injection | 10 mg/mL, 50 mL vial, pharmacy bulk package; unpreserved | Pepcid |
| Famotidine | Injection | 10 mg/mL, 2 mL vials; unpreserved | Pepcid |
| Famotidine | Tablet (Chewable) | 10 mg (OTC) | Pepcid AC (chewable) |
| Felodipine | Extended-release Tablets | 2.5 mg, 5 mg and 10 mg | Plendil ER |
| Fenofibrate | Capsules | 67 mg, 134 mg and 200 mg | Tricor |
| Fentanyl Citrate | Transdermal System | 0.6 mg/ 24 hr, 1.2 mg/ 24 hr, 1.8 mg/ 24 hr and 2.4 mg/ 24 hr | Duragesic |
| Fexofenadine Hydrochloride | Capsule | 60 mg | Allegra |
| Fexofenadine Hydrochloride | Tablets | 30 mg, 60 mg and 180 mg | Allegra |
| Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride | Tablet | 60 mg/ 120 mg | Allegra-D |
| Finasteride | Tablet | 5 mg | Proscar |
| Flecainide Acetate | Tablets | 50 mg, 100 mg and 150 mg | Tambocor |
| Fluconazole | Tablets | 50 mg, 100 mg, 150 mg and 200 mg | Diflucan |
| Fluconazole | For Oral Suspension | 50 mg/5 mL and 200 mg/ 5 mL | Diflucan for Oral Suspension |
| Flunisolide | Nasal Solution | 0.025% | Nasalide |
| Fluocinonide | Ointment | 0.05% | Lidex |
| Fluoxetine Hydrochloride | Tablets | 10 mg and 20 mg | Prozac |
| Fluoxetine Hydrochloride | Capsules | 10 mg, 20 mg and 40 mg | Prozac |
| Fluoxetine Hydrochloride | Delayed-release Capsule | 90 mg | Prozac Weekly |
| Fluoxetine Hydrochloride | Oral Solution | 20 mg (base)/ 5 mL | Prozac |
| Fluoxetine Hydrochloride | Capsules | 10 mg and 20 mg | Sarafem |
| Flutamide | Capsule | 125 mg | Eulexin |
| Fosinopril Sodium | Tablets | 10 mg, 20 mg and 40 mg | Monopril |
| Gabapentin | Capsules | 100 mg, 300 mg and 400 mg | Neurontin |
| Gabapentin | Tablets | 600 mg and 800 mg | Neurontin |
| Glipizide | Extended- | 10 mg | Glucotrol XL |

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| | release Tablet | | |
| Glyburide | Tablets | 1.5 mg, 3 mg, 4.5 mg and 6 mg | Glynase |
| Glyburide/Metformin Hydrochloride | Tablets | 1.25mg/ 250 mg, 2.5 mg/ 500 mg and 5 mg/ 500 mg | Glucovance |
| Hydrocodone Bitartrate and Ibuprofen | Tablet | 7.5 mg/ 200 mg | Vicoprofen |
| Ibuprofen | Chewable Tablets | 50 mg and 100 mg | Children's Motrin, Junior Strength Motrin |
| Ibuprofen | Oral Suspension | 100 mg/ 5 mL (Rx) | Motrin |
| Ibuprofen | Oral Suspension | 100 mg/ 5 mL (OTC) | Children's Motrin |
| Ibuprofen | Oral Drops | 40 mg/mL | Children's Motrin Drops |
| Ibuprofen and Pseudoephedrine Hydrochloride | Tablet | 200 mg/ 30 mg | Advil Cold and Sinus |
| Ifosfamide | For Injection | 1 g/vial and 3 g/vial | Ifex |
| Ifosfamide/Mesna | For Injection/ Injection Kit | 1 g/vial; 100 mg/mL, 10 mL vials and 3 g/vial; 100 mg/mL, 10 mL vials | Ifex/ Mesnex Kit |
| Ifosfamide/Mesna | Injection/ Injection Kit | 50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial | Ifex/ Mesnex Kit |
| Indomethacin | Extended-release Capsule | 75 mg | Indocin SR |
| Itraconazole | Capsule | 100 mg | Sporanox |
| Ketoprofen | Capsules | 25 mg, 50 mg and 75 mg | Orudis |
| Ketorolac Tromethamine | Injection | 15 mg/mL and 30 mg/mL | Toradol |
| Ketorolac Tromethamine | Ophthalmic Solution | 0.5% | Acular |
| Ketorolac Tromethamine | Tablet | 10 mg | Toradol |
| Lactulose | Oral Syrup | 10 g/15 mL | Cephalac |
| Lactulose | Oral Syrup | 10 g/15 mL | Chronulac |
| Lamotrigine | Tablets | 25 mg, 100 mg, 150 mg and 200 mg | Lamictal |
| Latanoprost | Ophthalmic Solution | 0.005% | Xalatan |
| Leuprolide Acetate | Injection (depot) | 7.5 mg/vial | Lupron Depot |
| Levofloxacin | Tablets | 250 mg, 500 mg and 750 mg | Levaquin |
| Loperamide HCl and Simethicone | Tablet | 2 mg/ 125 mg | Imodium Advanced |
| Loratadine | Tablet | 10 mg | Claritin |
| Loratadine | Oral Syrup | 1 mg/mL | Claritin |
| Loratadine/ Pseudoephedrine | Extended-release Tablet | 5 mg/ 120 mg | Claritin D- 12 hour |
| Loratadine/ Pseudoephedrine | Extended-release Tablet | 10 mg/ 240 mg | Claritin D-24 hour |

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| Loratidine | Orally Disintegrating Tablet | 10 mg | Claritin RediTabs |
| Mefloquine Hydrochloride | Tablet | 250 mg | Lariam |
| Megestrol Acetate | Oral Suspension | 40 mg/mL | Megace |
| Metoclopramide Hydrochloride | Injection | 5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials | Reglan |
| Mirtazapine | Tablets | 15 mg, 30 mg, and 45 mg | Remeron |
| Mirtazapine | Orally Disintegrating Tablets | 15 mg and 30 mg | Remeron SolTab |
| Moexipril Hydrochloride | Tablets | 7.5 mg and 15 mg | Univasc |
| Nabumetone | Tablets | 500 mg and 750 mg | Relafen |
| Naproxen Sodium | Extended-release Tablets | 375 mg (base) and 500 mg (base) | Naprelan |
| Nefazodone HCl | Tablets | 50 mg, 100 mg, 150 mg 200 mg and 250 mg | Serzone |
| Niacin | Extended-release Tablets | 500 mg, 750 mg and 1000 mg | Niaspan |
| Nicotine | Transdermal System | 7 mg/day, 14 mg/day and 21 mg/day | Habitrol |
| Nifedipine | Capsules | 10 mg and 20 mg | Procardia |
| Nifedipine | Extended-release Tablets | 30 mg, 60 mg and 90 mg | Adalat CC |
| Nifedipine | Extended-release Tablets | 30 mg, 60 mg and 90 mg | Procardia XL |
| Nitroglycerin | Transdermal System | 0.1 mg/hr | Transderm-Nitro |
| Nitroglycerin | Transdermal System | 0.1 mg/hr, 0.2 mg/hr, 0.3 mg/hr, 0.4 mg/hr, 0.6 mg/hr and 0.8 mg/hr | Nitro-dur |
| Nizatidine | Capsules | 150 mg and 300 mg | Axid |
| Norethindrone/ Ethinyl Estradiol | Tablets | 0.5 mg/ 0.035 mg, 0.75 mg/ 0.035 mg and 1 mg /0.035 mg | Ortho-Novum 7/7/7, 21 and 28 day |
| Norethindrone Acetate/Ethinyl Estradiol | Tablet | 1 mg/ 0.005 mg | Femhrt |
| Norethindrone Acetate/Ethinyl Estradiol | Tablets | 1 mg/ 0.02 mg, 1 mg/ 0.03 mg and 1 mg /0.035 mg | Estrostep Fe |
| Norethindrone Acetate/Ethinyl Estradiol | Tablets | 1 mg/ 0.02 mg, 1 mg/ 0.03 mg and 1 mg /0.035 mg | Estrostep 21 |
| Norgestimate/ Ethinyl Estradiol | Tablets | 0.18 mg /0.035 mg, 0.215 mg /0.035 mg and 0.25 mg /0.035 mg | Ortho Tri-Cyclen, 21 and 28 day |
| Nortriptyline Hydrochloride | Capsules | 10 mg, 25 mg, 50 mg and 75 mg | Pamelor |
| Octreotide Acetate | Injection | 0.05 mg /mL, 0.1 mg /mL and 0.5 mg/mL, 1 mL vials | Sandostatin (Preservative-free) |
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| Octreotide Acetate | Injection | 0.2 mg/mL and 1 mg /mL, 5 mL vials | Sandostatin |
| Olanzapine | Tablets | 2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg | Zyprexa |
| Omeprazole | Delayed-release Capsules | 10 mg, 20 mg and 40 mg | Prilosec |
| Ondansetron Hydrochloride | Tablets | 4mg, 8 mg and 24 mg | Zofran |
| Oxazepam | Capsules | 10 mg, 15 mg and 30 mg | Serax |
| Oxycodone | Extended-release Tablets | 10 mg, 20 mg, 40 mg, 80 mg and 160 mg | Oxycontin |
| Paclitaxel | Injection | 6 mg/mL, 5 mL, 16.7 mL, 25 mL, 33.3 mL and 50 mL vials | Taxol |
| Pamidronate Disodium | For Injection | 30 mg/vial, 60 mg/vial and 90 mg/vial | Aredia |
| Pamidronate Disodium | Injection | 30 mg/vial, 60 mg/vial and 90 mg/vial | Aredia |
| Paroxetine Hydrochloride | Tablets | 10 mg, 20 mg, 30 mg and 40 mg | Paxil |
| Paroxetine Hydrochloride | Capsules | 10 mg and 20 mg | Paxil |
| Pergolide Mesylate | Tablets | 0.05 mg, 0.25 mg and 1 mg | Permax |
| Potassium Chloride | Extended-release Tablets | 10 mEq and 20 mEq | K-Dur |
| Potassium Chloride | Extended-release Capsules | 8 mEq and 10 mEq | Micro K |
| Pravastatin Sodium | Tablets | 10 mg, 20 mg, and 40 mg | Pravachol |
| Prazosin Hydrochloride | Capsules | 1 mg, 2 mg and 5 mg | Minipress |
| Prednisolone Sodium Phosphate | Oral Solution | 5 mg(base)/ 5 mL and 15 mg (base)/ 5 mL | Pediapred |
| Propofol | Injection | 10 mg/mL ; 20 mL, 50 mL and 100 mL vials and 20 mL syringe | Diprivan |
| Propranolol Hydrochloride | Extended-release Capsules | 60 mg, 80 mg, 120 mg and 160 mg | Inderal LA |
| Quinapril Hydrochloride | Tablets | 5 mg, 10 mg, 20 mg and 40 mg | Accupril |
| Quinapril Hydrochloride/Hydrochlorothiazide | Tablets | 10 mg/ 12.5 mg, 20 mg/ 12.5 mg and 20 mg/ 25 mg | Accuretic |
| Ranitidine | Injection | 25 mg/mL, 2 mL and 6 mL and 40 mL vials | Zantac |
| Ranitidine | Tablets | 75 mg, 150 mg and 300 mg | Zantac |
| Ranitidine | Capsules | 150 mg and 300 mg | Zantac |
| Ranitidine | Oral Solution | 15 mg/mL | Zantac |
| Ribavirin | Capsule | 200 mg | Rebetol |
| Sertraline Hydrochloride | Tablets | 25 mg, 50 mg and 100 mg | Zoloft |

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| Sevoflurane | Inhalation | 100%, 250 mL | Ultane |
| Silver Sulfadiazine | Cream | 1% | Silvadene |
| Simvastatin | Tablets | 5 mg, 10 mg, 20 mg, 40 mg and 80 mg | Zocor |
| Tamoxifen Citrate | Tablets | 10 mg and 20 mg | Nolvadex |
| Terazosin Hydrochloride | Capsules | 1 mg, 2 mg, 5 mg and 10 mg | Hytrin |
| Terazosin Hydrochloride | Tablets | 1 mg, 2 mg, 5 mg and 10 mg | Hytrin |
| Terfenadine | Tablet | 60 mg | Seldane |
| Ticlopidine Hydrochloride | Tablet | 250 mg | Ticlid |
| Timolol Maleate | Ophthalmic Solution | 0.25% and 0.5% | Timoptic |
| Torsemide | Tablets | 5 mg, 10 mg, 20 mg, and 100 mg | Demadex |
| Tramadol Hydrochloride | Tablet | 50 mg | Ultram |
| Trazodone Hydrochloride | Tablet | 150 mg | Desyrel |
| Tretinoin | Cream | 0.025%, 0.05% and 0.1% | Retin-A |
| Tretinoin | Gel | 0.025% | Retin-A |
| Triamterene/ Hydrochlorothiazide | Tablets | 37.5 mg/ 25 mg and 75 mg/ 50 mg | Maxzide |
| Vecuronium Bromide | For Injection | 10 mg/vial and 20 mg/vial | Norcuron |
| Verapamil Hydrochloride | Extended-release Capsules | 120 mg, 180 mg and 240 mg | Verelan SR |
| Verapamil Hydrochloride | Extended-release Tablet | 180 mg | Isoptin SR |
| Vincristine Sulfate | Injection | 1 mg/mL, 1 mL, 2 mL and 5 mL vials | Oncovin |
| Zidovudine | Capsule | 100 mg | Retrovir |



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